

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION5 77 WEST JACKSON BOULEVARD CHICAGO, IL 60604-3590

AUG 1 0 2004

REPLY TO THE ATTENTION OF AE-17J

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Michael A. Nash 3M Office of General Counsel 3M Center, Building 0220-11-W-02 P.O. Box 33428 St. Paul, Minnesota 55133-3428

> Re: 3M Company Consent Order

Dear Mr. Nash:

Enclosed is an executed original of a Consent Order regarding the above captioned case.

If you have any questions about the Order, please contact me at (312) 886-0555.

Sincerely yours,

Linda H. Rosen, Chief

Air Enforcement and Compliance Assurance Section MI/WI

Enclosure

cc: Ken Ramm, Environmental, Health, Safety and Regulatory Manager 3M Company Specialty Materials Manufacturing Division 22614 Route 84 North Cordova, Illinois 61242

Julie Armitage, Section Manager Compliance and Systems Management Section Illinois Environmental Protection Agency 1021 North Grand Avenue Springfield, Illinois 62702

Mike Knobloch, District Engineer Illinois Environmental Protection Agency 1630 - 5th Avenue Moline, Illinois 61265

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 5

IN THE MATTER OF:)
)
3M Company) Administrative Consent Order
22614 Route 84 North)
Cordova, Illinois 61242) EPA-5-04-113(a) IL-07
)
Proceeding Pursuant to)
Section 113(a)(3))
of the Clean Air Act,)
42 U.S.C. §§ 7413(a)(3))

Administrative Consent Order

1. The Director of the Air and Radiation Division, United States Environmental Protection Agency (U.S. EPA), Region 5, is issuing this Order under Sections 113(a)(3) and 114(a)(1) of the Clean Air Act (Act), 42 U.S.C. §§ 7413(a)(3) and 7414(a)(1).

Statutory and Regulatory Background

- 2. Section 112 of the Act, 42 U.S.C. § 7412, authorizes the Administrator of U.S. EPA to promulgate regulations establishing National Emission Standards for Hazardous Air Pollutants (NESHAPs).
- 3. The NESHAP for Pharmaceuticals Production was proposed on April 2, 1997, became final on September 21, 1998, and is codified at 40 C.F.R. Part 63, Subpart GGG. The owner or operator of an existing affected source must comply with the provisions of this NESHAP no later than October 21, 2002, as required under 40 C.F.R. § 63.1250(f)(1).
- 4. The NESHAP for Pharmaceuticals Production, at 40 C.F.R. § 63.1250(a)(1), defines an affected source as a pharmaceutical manufacturing operation that: a) manufactures a pharmaceutical product; b) is located at a plant site that is a major source as defined in Section 112(a) of the Clean Air Act; and c) processes, uses or produces Hazardous Air Pollutants (HAPs).

- 5. The NESHAP, at 40 C.F.R. § 63.1257(a)(1), requires the owner or operator of a control device to address the composition and organic HAP concentration of the vent stream entering the control device in a design evaluation.
- 6. The NESHAP, at 40 C.F.R. § 63.1257(a)(1)(iii), requires the owner or operator of a condenser to consider the vent stream flow rate, relative humidity, and temperature in the design evaluation so that the design outlet organic HAP compound concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet are established. The temperature of the gas stream exiting the condenser must be measured and used to establish the outlet organic HAP concentration.
- 7. The NESHAP, at 40 C.F.R. § 63.1257(d)(3)(iii)(A), requires an owner or operator, during periods in which a condenser functions as an air pollution control device, to calculate controlled emissions using the emission estimation equations.
- 8. The NESHAP, at 40 C.F.R. § 63.1257(d)(3)(iii)(B), requires the owner or operator to demonstrate that a condenser, during periods when the condenser is operating as a process condenser, is properly operated, if the process condenser meets either of the criteria described in 40 C.F.R. § 63.1257(d)(3)(iii)(B)(1) and (2).
- 9. The NESHAP, at 40 C.F.R. § 63.1258(a), requires an owner or operator to provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance.
- 10. The NESHAP, at 40 C.F.R. § 63.1258(b)(1)(i), requires an owner or operator of control devices that control vent stream emissions totaling less than 1 ton per year HAP emissions, before control, to conduct monitoring consisting of daily verification that the devices are operating properly.
- 11. The NESHAP, at 40 C.F.R. § 63.1256(a), requires the owner or operator to identify, for each point of determination, wastewater streams meeting the criteria specified in 40 C.F.R. § 63.1256(a)(1)(i)(A) through (C).
- 12. Section 113(a)(3) of the Act, 42 U.S.C. § 7413(a)(3), authorizes the Administrator of U.S. EPA to issue an order requiring compliance with the NESHAPs regulations to any person who has violated or is in violation of the NESHAPs regulations. The Administrator has delegated the authority to issue these orders to the Director of the Air and Radiation Division.
- 13. The Administrator of U.S. EPA may require any person who owns or operates an emission source to provide information required by the Administrator under Section 114(a)(1) of the Act. The Administrator has delegated this authority to the Director of the Air and Radiation Division.

Findings

- 14. 3M Company owns and operates a chemical plant at 22614 Route 84 North in Cordova, Illinois 61242.
- 15. At the Cordova plant, 3M Company has a pharmaceutical manufacturing operation consisting of two production lines that manufacture pharmaceutical products within the meaning of the NESHAP for Pharmaceuticals Production. The Cordova plant site is a major source as defined in Section 112(a) of the Act. And, 3M Company uses HAPs at various stages of its pharmaceutical manufacturing process. Therefore, 3M Company is subject to the requirements of the NESHAP for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG.
- 16. The Cordova plant constitutes an "emission source" within the meaning of Section 114(a)(1) of the Act. Therefore, 3M Company is subject to the requirements of Section 114(a)(1).
- 17. On August 11, 2003, U.S. EPA issued to 3M Company a Finding of Violation alleging that 3M Company violated the NESHAP for Pharmaceutical Production at the Cordova plant by failing to adequately test, monitor, and keep required records regarding certain equipment at the facility. In the FOV, U.S. EPA alleged, inter alia, that:
 - a. 3M Company has not performed an initial compliance demonstration for process condensers associated with its pharmaceutical production processes, as required by 40 C.F.R. § 63.1257(d)(3)(iii)(B).
 - b. 3M Company has not identified control devices associated with its pharmaceutical production processes, as required by 40 C.F.R. § 63.1257(d)(3)(iii)(A), 40 C.F.R. § 63.1260(f)(5), 40 C.F.R. § 63.1258(a), 40 C.F.R. § 63.1258(b)(1), 40 C.F.R. § 63.1258(b)(1)(iii), 40 C.F.R. § 63.1258(b)(3)(i), and 40 C.F.R. § 63.1258(b)(3)(ii).
 - c. 3M Company has not performed design evaluations on the control devices used in its pharmaceutical production processes, as required by 40 C.F.R. § 63.1257(a)(1) and 40 C.F.R. § 63.1257(a)(1)(iii).
 - d. 3M Company failed to identify wastewater streams generated from its pharmaceutical production processes, as required by of 40 C.F.R. § 63.1256(a) and 40 C.F.R. § 63.1256(a)(1).
- 18. On September 17, 2003, representatives of 3M Company and U.S. EPA held a conference to discuss the August 11, 2003 Finding of Violation.
- 19. After a review of the information that 3M Company provided to U.S. EPA and after a thorough investigation of all relevant facts, U.S. EPA finds that the following requirements are necessary to assure compliance with the NESHAP at 3M Company's Cordova plant.

Compliance Program

- 20. By the effective date of this Order, 3M Company shall implement the following activities to achieve, demonstrate and maintain compliance with the NESHAP for Pharmaceutical Production at its Cordova, Illinois facility.
- 21. 3M Company shall submit a testing protocol for monitoring the exhaust gas temperature of the condenser within thirty (30) days from the date that a final Order is received. The testing shall be completed within forty-five (45) days from the date that the testing protocol is approved by EPA. Upon completion of the testing, a final report summarizing the results must be submitted within sixty (60) days in the form of a design evaluation from the date that the testing is completed.
- 22. 3M Company shall submit a testing protocol for the wastewater effluent stream(s) within thirty (30) days from the date that a final Order is received. The testing shall be completed within forty-five (45) days from the date that the testing protocol is approved by EPA. Upon completion of the testing, a final report summarizing the results must be submitted within sixty (60) days from the date that the testing is completed.
 - 23. 3M Company shall send all reports required by this Order to:

Attention: Compliance Tracker (AE-17J)
Air Enforcement and Compliance Assurance Branch
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604

General Provisions

- 24. This Order does not affect 3M Company's responsibility to comply with other local, state and federal laws and regulations.
- 25. Nothing in this Order limits U.S. EPA's authority to seek appropriate relief, including penalties under Section 113 of the Act, for any violation by 3M Company of the NESHAP for Pharmaceuticals Production, including the violations alleged in the August 22, 2004 Finding of Violation.
- 26. Nothing in this Order shall be construed to restrict U.S. EPA's authority under Section 114 of the Act, 42 U.S.C. § 7414.
- 27. Failure to comply with this Order may subject 3M Company to penalties of up to \$27,500 per day for each violation pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b).

- 28. The provisions of this Order shall apply to and be binding upon 3M Company, its officers, directors, agents, servants, employees, assignees and any successors in interest. 3M Company shall give notice of this Order to any successors in interest, prior to transfer of ownership, and shall simultaneously verify to U.S. EPA, at the above address, that 3M Company has given the notice.
- 29. This request is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., because it seeks collection of information by an agency from specific individuals or entities as part of an administrative action or investigation.
- 30. U.S. EPA may use any information collected pursuant to this Order in support of an administrative, civil or criminal action against 3M Company.
 - 31. 3M Company agrees to the terms of this Order.
- 32. This Order is effective on the date of signature by the Director of the Air and Radiation Division. This Order will expire one year from the effective date, provided that 3M Company has complied with all of its terms.

27 July 2004 Date

David Boaz

Plant Manager 3M Cordova

August 92004

Stephen Rothblatt, Director Air and Radiation Division

Enclosure

CERTIFICATE OF MAILING

I, Shanee Rucker, certify that I sent the Administrative Consent Order, EPA Order

No. EPA-5-04-113(a) IL-07, by Certified Mail, Return Receipt Requested, to:

Michael A. Nash 3M Office of General Counsel 3M Center, Building 0220-11-W-02 P.O. Box 33428 St. Paul, Minnesota 55133-3428

I also certify that I sent a copy of the Administrative Consent Order, EPA Order

No. EPA-5-04-113(a) IL-07, by First Class Mail to:

Julie Armitage, Section Manager Compliance and Systems Management Section Illinois Environmental Protection Agency P.O. Box 19506 Springfield, Illinois 62794-9506

Emilio Salis, Regional Manager Region 1 Illinois Environmental Protection Agency 9511 West Harrison Street Des Plaines, Illinois 60016

on the 10 day of August 2004.

Shanee Rucker,

Administrative Program Assistant

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AECAS (MI/WI)